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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,236	08/02/2001	Tony E. Hugli	SCRIP1460	8664

7590 07/28/2004

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EXAMINER

NOLAN, PATRICK J

ART UNIT PAPER NUMBER

1644

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

819

Office Action Summary

Application No.	Applicant(s)	
09/922,236	HUGLI ET AL.	
Examiner	Art Unit	
Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Part III DETAILED ACTION

1. Claims 1-72 are pending.
2. Applicant's election of Groups I-II in the reply filed on 8-18-03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. It is acknowledged that the original setting forth Groups I-II in one line was potentially misleading. To set the record straight a new restriction is set forth below to clear up any miscommunication. The time delay is regretted.

Restriction/Election

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-2, 4-13, 15-17, 20-21, 25-26, 30-33, 34-40, drawn to a method of detecting liver damage with either an antibody, classified in class 435, subclass 7.1.

Group II. Claims 1-3, 5-19, 25-46, drawn to a method of detecting liver damage by detecting enzymatic activity of kallikrein-like peptidase, classified in class 435 subclass 4.

Group III. Claims 22 and 23, drawn to a kit with an enzyme detection reagent and an alpha-2-macroglobulin detection reagent, classified in class 435, subclass 975.

Group IV. Claim 22 and 24, drawn to a kit with an enzyme detection reagent and an C4a or C3a detection reagent.

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Group V. Claims 47-56, drawn to a screening assay with sample derived from patients, classified in class 435 subclass 4.

Group VI. 57-61, drawn to detecting liver damage with detection reagents specific for each member of a liver damage panel, classified in class 435 subclass 4.

Group VII. 62-72, drawn to an in vitro screening assay with cultured cells, classified in class 435 subclass 29.

The inventions are distinct, each from the other because of the following reasons:

5. Groups I-II and V-VII are unique methods. They differ with respect to ingredients and method steps and represent patentably distinct subject matter.

Groups III-IV are unique products. They differ with respect to their physicochemical properties and are therefore patentably distinct.

Groups I-II or V-VII and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the products as claimed, the detection reagents can be used in either detection or screening method with either antibodies or peptides.

6. Because a search of these seven distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the examiner.

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SPECIES

This application contains claims directed to the following patentably distinct species of the claimed invention.

If groups I or II is elected the following species election is required.

A) a specific type of liver damage as recited in claims 9-13, 16 and 33-38

Each disease or state has unique physical, chemical and biological properties, which gives each species unique enablement and search requirements. The species are therefore patentably distinct from one another.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for which prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-8, 14-15, 17-21, 25-32 and 39-46 are generic.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor or at least one claim remaining in the application. Any amendment of the inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (h).


13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.


Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

July 26, 2004